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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/486,703	06/27/2000	IAN ROSS DOYLE	13704/2	9876

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EXAMINER	
DUFFY, PATRICIA ANN	
ART UNIT	PAPER NUMBER
1645	

MAIL DATE	DELIVERY MODE
04/30/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/486,703	DOYLE ET AL.	
	Examiner	Art Unit	
	Patricia A. Duffy	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 January 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *51-72* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *51-72* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2-9-09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

RESPONSE TO AMENDMENT

The response filed 1-7-09 has been entered into the record. Claims 51-72 are pending and are under examination.

The text of Title 35 of the U.S. Code not reiterated herein can be found in the previous office action.

Rejections Maintained

Claims 51-64 stand rejected under 35 U.S.C. 102(b) as being anticipated by Doyle et al (Advances in Critical Care Testing, Eds. Muller and McQueen, Springer-Verlag Telos, January 1997; reference A17 on the PTOL-1449 of 10-18-00) for all the reasons made of record and those herein.

Claims 51-72 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Doyle et al Am. J. Respir. Crit. Card. Med. 1994l 149;A576; of record hereinafter Doyle A.) in view of Doyle et al (Advances in Critical Care Testing, Eds. Muller and McQueen, Springer-Verlag Telos, January 1997; of record hereinafter Doyle B), Doyle et al (Am. J. Respir. Crit. Care. Med. 152:307-317, 1995; of record hereinafter Doyle C), Honda (Japanese Journal of Thoracic Diseases, 34 Suppl. Abstract only, December 1996; of record) and Abe et al (Japanese Journal of Thoracic Diseases, 33(11):1219, Abstract only, November 1995; of record) for all the reasons made of record and those herein.

Applicant's arguments are in sum that Doyle et al does not disclose or suggest that a member of the normal or other disease group are necessarily asymptomatic to lung damage or alveolo-caplliary membrane damage or necessarily of a condition that the clinical diagnosis of lung damage or alveolo-capillary membrane damage in the individual con not be otherwise confirmed without the aid of one or more invasive procedures. This is not persuasive because one skilled in the art of diagnostic medicine clearly an unambiguously

defines normal as "typical; usual; healthy; according to the rule or standard" (Stedman's medical dictionary 24th edition, 1988, page 960). This interpretation is consistent with that of laboratory medicine that states "… the standard of comparison for a test result was the "normal" value or the normal range. In this context, the word normal was intended to indicate the values were the usual, customary, or typical ones that were associated with good health (Holmes in Manual of Clinical Laboratory Immunology, 1997, page 1158, column 1, second full paragraph). Therefore, applicants arguments that there is no evidence that the normals were not in fact normal or asymptomatic to lung damage is clearly inconsistent with the use of normal in the context of diagnostic medicine as normal is healthy. Applicants again argue that no evidence of cardiorespiratory disease is not equivalent of no evidence of lung damage or asymptomatic and that the patient populations are different. This is not persuasive because the patient populations are not clearly different. No evidence of cardiorespiratory disease necessarily includes patient populations that are asymptomatic to lung damage or alveolo-capillary membrane damage without invasive procedures because they have *no evidence of cardiorespiratory disease*. Applicants indicate that they have argued that the prior art does not identify the screened patient population as those with asymptomatic lung or membrane disease. This argument is inconsistent with the method of screening for patients with asymptomatic lung or membrane disease. If one could identify such as abnormal without the test, one would not need to test. The test is a "screen" for an increase. The tested individual need not have an increase to meet the screening test and the screen need not actually "detect" an increase and associate the detected increase with a diagnostic outcome. The claim is not drawn to any active process steps that actually detects an increase in an individual biological sample and correlating that increase to a specific disease state. "Screening" is not defined in the specification to necessarily detect an increase and correlate the increase to a disease state. Applicants again argue the degree of analysis of normal. Applicant's arguments are inconsistent with the definition as used in the art. Applicants

argue a degree of analysis that is not set forth either in the prior art nor in the specification as filed. During patent examination, the claims are given the broadest reasonable interpretation consistent with the specification. See *In re Morris*, 127 F.3d 1048, 44 USPQ2d 1023 (Fed. Cir. 1997). The specification did not place any particular evaluation of "normal" or the argued patient population. As such, the position on normal or no evidence of caridorespiratory disease is consistent with that applied by the diagnostic and laboratory arts. Applicants again argue the Remy-Jardin et al article providing evidence that smokers appearing healthy did have overt lung disease that could be diagnosed without the aid of invasive procedures. This is not persuasive because the fact remains that there is overlap in the patient populations and applicants have not provided evidence that the art was drawn to patients not in the group.

The rejection is maintained.

Applicant's arguments with respect to the 103 of record are predicated on the failure of Doyle A above and since Doyle A does not fail for either the normal or OD issue, the obviousness issues based thereon do not fail.

The rejection is maintained.

Status of Claims

Claims 51-72 are rejected.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A. Duffy whose telephone number is 571-272-0855. The examiner can generally be reached on M-Th 7:30 am - 6:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisors, Robert Mondesi can be reached at 571-272-0956.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Patricia A. Duffy/
Primary Examiner